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| APPLICATION NO.       | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|-----------------------|-------------|----------------------|---------------------|-----------------|
| 10/009,151            | 04/16/2002  | Takashi Shigematsu   | 13723-002001        | 8643            |
| 7590 04/05/2005       |             |                      | EXAMINER            |                 |
| Y Rocky Tsao          |             |                      | LUM, LEON YUN BON   |                 |
| Fish & Richard        | son         |                      |                     | <del></del> _   |
| 225 Franklin Street   |             |                      | ART UNIT            | PAPER NUMBER    |
| Boston, MA 01110-2804 |             |                      | 1641 .              |                 |

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|   | •  |   |   |  |  |  |
|---|--|---|---|--|--|--|
| Office Action Summary   |  | Application No.   | Applicant(s)  |  |  |  |
|   |  | 10/009,151  | SHIGEMATSU ET AL.   |  |  |  |
|   |  | Examiner  | Art Unit  |  |  |  |
|   |  | Leon Y. Lum   | 1641  |  |  |  |
| Period fo   | The MAILING DATE of this communication app<br>or Reply   | ears on the cover sheet with  | the correspondence address  |  |  |  |
| A SH<br>THE<br>- Exte<br>after<br>- If the<br>- If NC<br>- Failu<br>Any   | ORTENED STATUTORY PERIOD FOR REPLY MAILING DATE OF THIS COMMUNICATION. nsions of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. a period for reply specified above is less than thirty (30) days, a reply operiod for reply is specified above, the maximum statutory period we are to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b). | 36(a). In no event, however, may a reply within the statutory minimum of thirty (3 vill apply and will expire SIX (6) MONTHs cause the application to become ABAN | be timely filed  0) days will be considered timely.  S from the mailing date of this communication.  DONED (35 U.S.C. § 133). |  |  |  |
| Status  |  |   |   |  |  |  |
| 1)⊠   | Responsive to communication(s) filed on <u>05 Ja</u>   | nuary 2005.   |   |  |  |  |
| 2a) <u></u>   | This action is <b>FINAL</b> . 2b) This action is non-final.  |   |   |  |  |  |
| 3)  | Since this application is in condition for allowance except for formal matters, prosecution as to the ments is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.   |   |   |  |  |  |
| Disposit  | ion of Claims  |   |   |  |  |  |
| 5)  | Claim(s) <u>22-57</u> is/are pending in the application 4a) Of the above claim(s) is/are withdraw Claim(s) is/are allowed.  Claim(s) is/are rejected.  Claim(s) is/are objected to.  Claim(s) <u>22-57</u> are subject to restriction and/or   | vn from consideration.  |   |  |  |  |
| Applicat  | ion Papers   | ·   |   |  |  |  |
| 9)☐ The specification is objected to by the Examiner.   |  |   |   |  |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.   |  |   |   |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |  |   |   |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. |  |   |   |  |  |  |
| Priority (  | under 35 U.S.C. § 119  |   |   |  |  |  |
| a)  | Acknowledgment is made of a claim for foreign  All b) Some * c) None of:  1. Certified copies of the priority documents  2. Certified copies of the priority documents  3. Copies of the certified copies of the priority documents  application from the International Bureau  See the attached detailed Office action for a list   | s have been received.<br>s have been received in App<br>ity documents have been re<br>i (PCT Rule 17.2(a)).   | lication No<br>ceived in this National Stage  |  |  |  |
| Attachmen   |  |   |   |  |  |  |
|   | e of References Cited (PTO-892)<br>e of Draftsperson's Patent Drawing Review (PTO-948)   |   | mary (PTO-413)  |  |  |  |
| 3) 🔲 Infori   | mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) or No(s)/Mail Date  |   | lail Date mal Patent Application (PTO-152)  |  |  |  |

## **DETAILED ACTION**

The amendment filed 03 January 2005 is acknowledged and has been entered.

2. The Declaration under 37 C.F.R. 1.132 is acknowledged and has been entered.

## Election/Restrictions

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 22-24, drawn to a method for producing denatured lipoprotein.

Group II, claim(s) 27-29, drawn to a method for producing a stabilized denatured lipoprotein.

Group III, claim(s) 32-34, drawn to a method for producing stabilized denatured lipoprotein.

Group IV, claim(s) 25-26, 52, and 55, drawn to a denatured lipoprotein.

Group V, claim(s) 30-31, 53, and 56, drawn to a stabilized denatured lipoprotein.

Group VI, claim(s) 35-36, 54, and 57, drawn to a stabilized denatured lipoprotein.

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Group VII, claim(s) 37-41, drawn to a method for determining denatured lipoprotein in a sample.

Group VIII, claim(s) 42-46, drawn to a method for determining denatured lipoprotein in a sample.

Group IX, claim(s) 47-51, drawn to a method for determining denatured lipoprotein in a sample.

4. The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-IX appears to be a denatured protein produced by freezing a solution containing lipoprotein and melting the frozen solution.

However, Belzner et al (US 3,632,473) teach freezing and quick thawing of plasma to denature lipoproteins. See column 6, lines 54-65.

Therefore, the technical feature linking the inventions of Groups I-IX does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art. Accordingly, Groups I-IX are not linked by the same or a corresponding special technical feature as to form a single general inventive concept.

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- 5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
- 6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- 7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on weekdays from 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leon Y Lum **Patent Examiner** 

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LYL

LONG V. LE SUPERVISORY PATENT EXAMINER **TECHNOLOGY CENTER 1600** 

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